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Responsive to Office Action mailed on 18 May 2006

#### REMARKS

##### **Amendment to the Claims**

Claim 40 has been amended to conform its wording to that of the other independent claims by adding the phrase "indicative of the level of dehydration" onto its end.

##### **Discrepancy between present claim rejections and present claims**

It is stated in the present Office Action that the "submission filed on 28 March 2006 has been entered". That submission was submitted together with a Request for Continued Examination and constituted a Reply in which original Claims 1-20 were cancelled and new Claims 21-40 were added. However, the present claim rejections refer to terms that do not appear in the present claims, e.g., "wearable article", "absorbent article", "specific gravity", and "measuring specific gravity". In fact, the present claim rejections appear to have been copied nearly *verbatim* from previous Office Actions, in which the original claims were pending. Despite this fact, a sincere attempt is made herein to respond to the present Office Action as if the rejections had been written to apply to the present claims.

##### **Claim Rejections Under 35 U.S.C. § 103 over Neading *et al.*, Hsu, and Flam**

Claims 21, 22, 24 through 30, and 32 through 40 were rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,515,194 to Neading *et al.* in view of U.S. Patent No. 5,922,283 to Hsu and further in view of U.S. Patent No. 5,181,905 to Flam.

According to MPEP § 2143:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

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The present rejections are hereby traversed on the ground that, by this standard, a *prima facie* case of obviousness has not been established with respect to any of the rejected claims on the basis of the cited references, for at least the following reasons.

Independent Claims 21, 37, and 40

The present set of claims contains three independent claims, which are **Claims 21, 37, and 40**. All of the other pending claims depend from these independent claims. In each of these three independent claims, the disposable diaper comprises a dehydration indicator comprising a chemical indicating composition providing a visible signal indicative of a level of dehydration in response to the ionic strength of urine exuded into the diaper by its wearer. In addition, the dehydration indicator either comprises an alphanumeric character indicative of the level of dehydration (in **Claims 21 and 40**) or else the visible signal itself forms an alphanumeric character indicative of the level of dehydration (in **Claim 37**). For reference, embodiments in which the dehydration indicator comprises an alphanumeric character in addition to the visible signal are shown in Figures 5, 7, and 8, while an embodiment in which the visible signal itself forms the alphanumeric character is shown in Figure 6.

On the other hand, the cited Neading *et al.*, Hsu, Flam, and Lee references, either singly or in combination, do not disclose structures equivalent or analogous to the structures that are claimed in the present claims. Therefore, their modification and/or combination would not create the claimed structure. (As was pointed out in the previous Reply, whether the proposal is to modify, to combine, or to modify and combine the prior art inventions was not clear in the previous Office Action; it is still not clear in the present Office Action.) In addition, there is no suggestion or motivation to modify and/or combine the references as proposed. Furthermore, the proposed modifications and/or combination would not be expected to be successful due to technical issues not addressed in any of the Office Actions. Also, the principles of operation of the cited prior art inventions were improperly changed in the proposed modification and/or combination. Finally, the cited prior art inventions were improperly rendered unsuitable for their intended purposes in the proposed modification and/or combination. Each of these failings of the present rejections is addressed below.

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Lack of disclosure of equivalent or analogous structure

It was admitted in the Final Action mailed on 27 January 2006 and again in the present Office Action, that "Neading, as modified by Hsu, fails to disclose the dehydration indicator comprising an alphanumeric character indicative of a level of dehydration". In an attempt to remedy this admitted deficiency, the Flam reference was added and it was alleged that "Flan [*sic*; Flam] teaches the use of letters and numbers to indicate a physical property of a liquid absorbed by an absorbent article, as shown in figure 3."

However, the sole embodiment in which Flam mentions "letters and numbers", *i.e.*, alphanumeric indicia, is one in which a commercially available *temperature sensitive liquid crystal tape 11* is attached onto the outside of a *wound dressing 31*. The numeric characters on this *temperature sensitive liquid crystal tape 11* do not indicate a level of dehydration, as required by the independent claims. Instead, they merely indicate the temperature of the surface onto which it is placed.

Lack of suggestion or motivation

It was stated in the Final Office Action mailed on 27 January 2006, and again in the present Office Action, that "[t]he use of letters and numbers as indicia allow [*sic*; allows] the user to more easily recognize a change in the property and administer appropriate treatment, as disclosed in column 4, lines 56-68". However, this statement in the Office Action represents the Examiner's conclusion rather than being an accurate characterization of Flam's disclosure. In fact, Flam does not even mention "letters and numbers" in the cited text. Instead, Flam merely explains that monitoring the temperature beneath a dressing can be useful in determining the stage of an underlying pressure sore, either as it worsens or as healing progresses, and administering appropriate treatment.

In addition, the characterization of the disclosure of Flam constitutes impermissible picking and choosing only so much of the reference's disclosure as will support the Examiner's position to the exclusion of other parts necessary to the full appreciation of what the reference fairly suggests to one skilled in the art. In particular, the allegation of obviousness was based on picking the general concept of *using alphanumeric characters* out of the context in which it was disclosed by

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Flam, namely the use of a *temperature sensitive liquid crystal tape* to indicate the temperature of a surface, and improperly superimposing this general concept onto the disclosures of Neading *et al.* and Hsu, both of which disclose *chemical reactions to urine*. This approach is in direct contradiction to the decision in *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448 (Fed. Cir. 1986) (citations omitted) ("It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art."). In this instance, no explanation was provided in the Office Actions of how one of skill in the present field of art would view Flam's disclosure of the use of a *temperature sensitive liquid crystal tape* as being useful when contemplating how to provide a visible signal in response to the ionic strength of urine.

Lack of expectation of success

Despite the obvious technical issues, no explanation was provided in the Final Office Action mailed on 27 January 2006 or the present Office Action with respect to how the chemically reactive *reagent test strip* of Hsu could be either combined with or replaced by the non-chemically reactive temperature sensitive liquid crystal tape of Flam. Likewise, no explanation was provided as to how the *temperature sensitive liquid crystal tape* could be used to indicate anything in response to urine ionic strength. Instead, it was merely stated that "[i]t would...be obvious...to provide the indicator...with alphanumeric characters". Thus, in the present rejection, the generic concept of *indicating something alphanumerically* was extracted from the specific example of the commercially available *temperature sensitive liquid crystal tape* and applied with a broad brush, without even a hint as to how the *wetness indicator* of Neading *et al.* turned *reagent test strip* of Hsu could be made to indicate alphanumerically.

Merely pointing out that one reference discloses something falls short of demonstrating the desirability and practicality of incorporating it into a modification of another reference, much less demonstrating that the incorporation will create the desired result. Specifically, merely pointing out that one reference discloses indicating a surface temperature alphanumerically falls short of demonstrating the desirability or practicality of modifying another reference to indicate a chemical reaction alphanumerically, especially when there are such fundamental differences as

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the parameter being measured by heat conduction at a surface in one reference *versus* resulting from a chemical reaction with urine in the other reference.

In light of the above, it is clear that one of skill in the art would not expect success in making the proposed modification and/or combination.

Improper changing of principle of operation of prior art invention

According to MPEP 2143.01, “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” Yet, each proposed modification and/or combination changed the principle of operation of the respective preceding invention.

Specifically, the *simple “on-off” wetness indication via chemical reaction with the urine* of Neading *et al.*, was changed to the different chemically reactive *complex range of color responses* of Hsu, and then the principle of operation of a chemical reaction with the urine was discarded entirely in order to substitute the non-chemically reactive temperature sensitive liquid crystal tape of Flam. Thus, it is clear that the principles of operation of the cited prior art inventions were improperly changed in the proposed modification and/or combination.

Improper rendering of prior art invention unsuitable for its intended purpose

Again according to MPEP 2143.01, “[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” Yet, each proposed modification and/or combination rendered the respective preceding prior art invention unsuitable for its intended purpose.

Specifically, the invention of Neading *et al.* was rendered unsuitable for its intended purpose of *providing a simple “on-off” indication of wetness* by substituting the complex color response of Hsu that *requires comparison to a color scale for its meaning to be deduced*, and then this intermediate modified “invention” was in turn rendered unsuitable for its intended purpose of

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*indicating a chemical property of the urine* by substituting the non-chemically reactive temperature sensitive liquid crystal tape of Flam. Thus, it is clear that the cited prior art inventions were improperly rendered unsuitable for their intended purposes in the proposed modification and/or combination.

#### Dependent Claims

All of the present dependent claims depend from the three independent claims discussed above, thereby containing all of the limitations of the respective independent claims. Therefore, the points discussed above with respect to the independent claims pertain to all of the dependent claims, as well. In addition, the following points bear comment.

#### Claims 24, 25, 32, 33, and 39

Each of **Claims 24, 32, and 39** contains the limitations that the chemical indicating composition, which is introduced in the respective independent claim from which it depends, provides a visible signal indicative of a level of dehydration in response to an ionic strength of the urine. In addition, in each of these claims, the dehydration indicator also comprises a **second chemical indicating composition** providing a **second visible signal** in response to the ionic strength. **Claims 25 and 33** depend respectively from **Claims 24 and 32** and thereby contain the same limitations.

The entire basis for the rejection of these five claims was a statement in the present Office Action that "the visible signal for a second level of ionic strength is represented by a different color". None of the cited Neading *et al.*, Hsu, Flam, and Lee references was cited. Therefore, it can only be surmised that perhaps the disclosure of Hsu was interpreted in this way, since Neading *et al.* do not disclose different colors and Flam does not disclose any visible signal whatsoever in response to ionic strength. Hsu does indeed disclose that different colors will appear at different levels of ionic strength. However, these different colors are produced by a single chemical indicating composition in every disclosed embodiment. Specifically, the single chemical composition provides a particular color response at a particular ionic strength. Unlike the claimed diaper, Hsu does not disclose or suggest two chemical indicating compositions being

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used together, much less the provision of two visible signals by means of two chemical indicating compositions.

In addition, **Claim 39** contains the limitation that the second visible signal forms a **second alphanumeric character**. This limitation was not addressed in any way in the Office Action.

#### Claim 27

**Claim 27** contains the limitation that the indicating composition comprises bromothymol blue. However, this substance was not mentioned in the Office Action. Instead, it was alleged that Hsu discloses "bromophenol blue". Thus, the specific limitation of this claim was not addressed in the Office Action.

#### Claims 28 through 30

All three of **Claims 28 through 30** were rejected on the basis that "it would have been an obvious matter of design choice to place a colored shape juxtaposed with the alphanumeric character, since the added shape provides no particular purpose and solves no stated problem." However, this statement is inaccurate and directly contradictory to the clear disclosure and even to the claim wording, itself. In addition, none of the cited Neading *et al.*, Hsu, Flam, and Lee references was cited, *i.e.*, no similarity between the cited disclosures and the claimed invention was pointed out or alleged.

In **Claim 28**, the colored shape is not "added", as mischaracterized in the rejection. Instead, the colored shape is the form in which the visible signal appears. The visible signal is a fundamental aspect of the present invention. It is not merely some randomly "added" element lacking in purpose. Furthermore, it is clear from the description, including in the paragraph beginning on page 6 at line 24, that the appearance of the visible signal next to an alphanumeric indicium serves the purpose of apprising the viewer of specific information relative to the level of dehydration. For example, using the embodiment of Figure 5 as an example, the appearance of the visible signal in the form of a colored shape **85** next to the alphanumeric indicium **95** reading "MODERATE" serves to inform the viewer that a moderate level of dehydration has been detected. Similarly, in the embodiment of Figure 7, the appearance of the visible signal in

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the form of a colored shape 85 next to the alphanumeric indicium reading "1.020" serves to inform the viewer that a urine specific gravity of from about 1.020 to about 1.024 has been detected, and as disclosed on page 5 at lines 4 and 5, this condition corresponds to a mild level of dehydration.

In Claims 29 and 30, a colored zone, rather than a colored shape, is juxtapositioned with the alphanumeric character. This difference between the colored zone of Claims 29 and 30 and the colored shape of Claim 28 was not addressed in the rejection. Nevertheless, like the colored shape of Claim 28, the colored zone of Claims 29 and 30 is likewise not merely some randomly "added" element lacking in purpose. Instead, referring to the embodiment of Figure 8, the colored zones 96, together with the juxtapositioned alphanumeric indicia 95, form a color key serving the purpose of enabling the viewer to interpret the visible signal, which appears as a particular color of the indicating composition 70. By definition, lacking at least one colored zone, there could be no color key. While Claim 29 is most broadly directed to this class of embodiments, Claim 30 is more specifically directed to a version in which at least two colored zones are juxtapositioned with alphanumeric indicia to form the color key.

#### Claims 35 and 36

In Claim 35, the chemical indicating composition of Claim 21 is covered by a semipermeable membrane formed of, among several choices in a Markush group, cellulose acetate. For reference, such an embodiment is shown in Figures 3 and 4, where the semipermeable membrane 75 covers the indicating composition 70.

Both Claims 35 and 36 were rejected on the basis that "Neading shows in figure 1 a fluid transport means 14B comprising cellulose acetate, as disclosed in column 3, lines 31-47." Thus, the limitation of Claim 35 that the chemical indicating composition is covered by a semipermeable membrane was not addressed in the rejection. Despite this fact, it is surmised in light of the reference to the *central portion 14B* of the *fluid transport layer 14* of Neading *et al.* that it was intended to repeat the allegation from previous Office Actions that the *central portion 14B* of *fluid transport layer 14* covers the *peripheral edge 14A* of the same *fluid transport layer 14*. However, as has been explained in several previous Replies, by elementary geometry, the



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**central portion of an unfolded sheet does not “cover” its own edge.** In fact, the only way in which the term “cover” could be construed to make the *central portion 14B* “cover” the *peripheral edge 14A* of the *fluid transport layer 14* would be to distort the meaning of this term so unreasonably as to render the claim language meaningless, while simultaneously ignoring the clear disclosure of the intended meaning of the term in the present Application.

Summary with respect to rejections of Claims 21, 22, 24 through 30, and 32 through 40

The requirements for the establishment of a *prima facie* basis of obviousness have not been met with respect to any of Claims 21, 22, 24 through 30, and 32 through 40. Accordingly, it is requested that the rejections of these claims be withdrawn.

**Claim Rejection Under 35 U.S.C. § 103 over Neading *et al.*, Hsu, Flam, and Lee**

Claim 23 was rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,515,194 to Neading *et al.* in view of U.S. Patent No. 5,922,283 to Hsu and U.S. Patent No. 5,181,905 to Flam, and further in view of U.S. Patent No. 5,947,943 to Lee.

This rejection is hereby traversed on the ground that a *prima facie* case of obviousness has not been established with respect to Claim 23 on the basis of the cited references, for at least the following reasons.

Claim 23 contains the limitations that the dehydration indicator comprises a translucent cover, that this translucent cover masks the visible signal when the urine ionic strength is below the predetermined threshold, and that the signal becomes visible through the translucent cover when the ionic strength exceeds the threshold. For reference, such an embodiment is described on page 6 at lines 5 through 12.

It was admitted in the Final Action mailed on 27 January 2006, and again in the present Office Action, that “Neading, in combination with Hsu and Flam...remains silent with respect to the outer cover”. In an attempt to remedy the admitted deficiency, the Lee reference was added and it was alleged that it was obvious to cover the already-exposed *indicator 16* of Neading *et al.* with a translucent sheet like Lee’s translucent *back sheet 16*.

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Lack of disclosure of equivalent or analogous structure

The limitation of Claim 23 that the translucent cover masks the visible signal when the urine ionic strength is below the predetermined threshold was not addressed in the Office Action. Furthermore, there is no indication in Lee's disclosure that the *translucent moisture barrier layer 28* portion of the *back sheet 16* masks the visual appearance of the *wetness-indicating material 24* at any time or at any level of dryness or wetness. Instead, "the moisture barrier 28 is transparent or translucent, so that the visual appearance of the wetness-indicating material 24 can be perceived through the moisture barrier 28. As described previously, the wetness-indicating material will generally have a light appearance when dry and dark appearance when wet" (column 3, lines 46-58). Thus, it is clear that Lee's *moisture barrier 28* enables the underlying *wetness-indicating material 24* to be seen over its entire range of appearance from its dry condition to its wet condition, rather than only when some threshold is exceeded.

Lack of suggestion or motivation to add translucent cover

Throughout the prosecution of the present Application, at least one claim has contained a limitation that the claimed dehydration indicator comprises a translucent cover. In every Office Action, it has been alleged that it would have been obvious to make the *outer layer 22* of Neading *et al.* translucent as taught by Lee. In every response, it has been pointed out that Neading *et al.* explicitly teach away from following Lee's direction and that Neading *et al.* explicitly cite the Lee patent on which the rejections have been based in column 1 of their disclosure.

In particular, in the Office Action mailed on 28 May 2004, this proposal to make the *outer layer 22* of Neading *et al.* translucent was justified on the basis that doing so would make the *indicator 16* "easily viewed without removing the article". It is noted that this rationale was not provided by either Neading *et al.* or Lee, but instead was offered by the Examiner. This reasoning was refuted in the Reply dated 24 August 2004, where it was pointed out that the *indicator 16* of Neading *et al.* is already exposed and visible and, in fact, this constant visibility is a key point of the invention. It was also pointed out that Neading *et al.* explicitly teach away from reapplying the structure taught by Lee.

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Nevertheless, the same rejections were repeated in the Final Office Action mailed on 17 November 2004, this time on the altered basis that making the *outer layer 22* of Neading *et al.* translucent would “allow the entire article of Neading to be covered by the backsheet [*sic*; *outer layer 22*] while the indicator remains visible. Thus, Lee teaches an improvement to Neading”. This altered reasoning was refuted in the Reply dated 12 January 2005, where it was again pointed out that the *indicator 16* is already visible and that Neading *et al.* explicitly teach away from reapplying the structure taught by Lee.

These facts were inexplicably ignored and, in the Advisory Action mailed on 22 February 2005, it was stated that “figures 6 and 7 of Neading show the indicator within the boundaries of, and therefore covered by, the article 12, thus creating a need for a translucent cover through which the indicator may be seen”. This mischaracterization of the disclosure of Neading *et al.* was refuted in the Appeal Brief dated 13 April 2005, where it was pointed out that the element misidentified as the “article 12” is actually the *diaper substrate 12*, which comprises three layers between which the *fluid transport layer 14* is located, and that in a plan view as in Figures 6 and 7, the *fluid transport layer 14* will appear to be “within the boundaries” of the *diaper substrate 12*, but is still exposed, as explicitly disclosed throughout the description of Neading *et al.* and as clearly shown in the other figures showing views other than a plan view.

In the Examiner’s Answer mailed on 1 August 2005, the correctness of the above was acknowledged in the statement that the *indicator 16* is exposed. However, yet another basis for making the *outer layer 22* of Neading *et al.* translucent was raised. This time, it was stated that Lee’s outer cover “provides a barrier to moisture...which prevents liquids from leaking from the article and protects the indicator from exterior liquids”. It was then stated that by making the outer cover of Neading *et al.* translucent, the *indicator 16* would be “protected...but still easily viewed without removal of the article”. It was also stated in the same Examiner’s Answer that “the translucent outer cover of Lee would provide the additional advantage of protecting the otherwise exposed indicator of Neading, while still allowing the indicator to be visible from the outside”. It is noted that, as with the previous justification, this rationale was not provided by either Neading *et al.* or Lee, but instead was offered by the Examiner.

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This reasoning was refuted in the Reply dated 22 September 2005, where it was pointed out that Neading *et al.* provide no indication whatsoever that the exposure of their *indicator 16* is problematic, never mentioning any problem with regard to leakage or of any need to “protect” the *indicator 16*. It was also pointed out that Lee likewise fails to mention any such problem. Instead, in the Lee reference, it is essential that the *moisture barrier layer 28* of the *backsheet 16* be translucent because the wetness-indicating material 24 is disposed beneath and entirely covered by the moisture barrier layer 28 and would otherwise not be visible. As is explicitly recited at column 3, lines 53-55 of Lee, “the moisture barrier 28 is transparent or translucent, so that the visual appearance of the wetness-indicating material 24 can be perceived through the moisture barrier 28.” In other words, in the structure disclosed by Lee, the “visual indicator” that is the object of the invention would not be visible if the outermost layer of the *backsheet* were not translucent. Thus, the only suggestion or motivation provided by Lee relative to a translucent layer is that a layer that covers a “visual indicator” must be translucent so that the indicator beneath it can be seen. This fact is extremely basic; an object hidden behind another object cannot be seen if the overlying object is opaque. However, as previously explained, the *indicator 16* of Neading *et al.* is already visible and it is not covered. Therefore, the teaching of Lee to make a covering layer translucent is not relevant to the article of Neading *et al.*, in which the *indicator 16* is exposed rather than being covered.

Nevertheless, in the Final Office Action mailed on 27 January 2006 and in the present Office Action, the same allegations were repeated on the same basis as in the Examiner’s Answer, despite the fact that in every disclosed embodiment, without any modification, the wetness indicator of Neading *et al.* is already visible and so may be easily viewed without removing the article, thereby obviating any need for a translucent cover to enable the indicator to be seen.

Thus, the alleged motivation for making the outer cover of Neading *et al.* translucent does not, in fact, exist. Furthermore, the explicit consideration and rejection of the cited Lee reference by Neading *et al.* is the direct obverse of a suggestion to modify its own teachings or to combine them with the teachings of the rejected Lee reference. In other words, as pointed out in several responses, Neading *et al.* explicitly teach away from reapplying the structure taught by Lee,

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thereby precluding the establishment of a *prima facie* case of obviousness according to MPEP 2141.02 VI and 2145 X.D.

Summary with respect to rejection of Claim 23

The requirements for the establishment of a *prima facie* basis of obviousness have not been met with respect to Claim 23. Accordingly, it is requested that the rejection of this claim be withdrawn.

**Allowable Subject Matter**

It was stated in the Office Action that **Claim 31** would be allowable if rewritten in independent form. This claim has not been so rewritten in this Reply because it is believed that all of the pending claims are allowable in their present form.

**Summary of this Reply**

A claim has been amended.

The lack of basis for the rejections of the present claims over the cited references has been explained.

In light of the above, timely and favorable consideration of the pending claims and the issuance of a Notice of Allowance are requested.

Respectfully submitted,  
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24 July 2006

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